

## **REMARKS**

Claims 11-22, 24, 35-46 and 48 have been amended in accordance to the Examiner's comments. Claims 11-22, 24, 35-46 and 48 are currently pending. No new matter is added by this amendment. The following addresses the rejections set forth in the March 19, 2009 Office Action.

### **Rejection of Claims 11-22, 24, 35-46 and 48 Under 35 U.S.C. §112, first paragraph,**

#### **Enablement**

The Examiner rejected claims 11-22, 24, 35-46 and 48 under 35 U.S.C. §112, first paragraph, stating that for not enabling or providing a written description regarding the structure of a second DNA cassette in general. Specifically, the Office Action contends that Applicants' disclosure does not enable any person skilled in the art to make and/or use the invention commensurate in scope with the claims. This contention is respectfully traversed.

When a disclosure describes a claimed invention in a manner that permits one skilled in the art to reasonably conclude that the inventor possessed the claimed invention the written description requirement is satisfied. (MPEP §2163 (emphasis added)). This possession may be shown in any number of ways and Applicants need not describe every claim feature exactly because there is no in haec verba requirement. (MPEP § 2163). Rather, to satisfy the written description requirement, all that is required is "reasonable clarity." (MPEP § 2163.02). Also, an adequate description may be made in any way through express, implicit, or even inherent disclosures in the application, including words, structures, figures, diagrams, and/or formulae. (MPEP §§ 2163(I), 2163.02).

As the amended, independent claims 11 and 35 now recite a second DNA cassette comprising heterospecific site-specific recombinase target sites that are homospecific and in the

same orientation with the wild-type/non-mutated or a mutated target site of a site-specific recombinase of the first cassette at one end and a mutated target site of said site-specific recombinase homospecific to said recombinase target site of the first cassette at an other end, with said target sites of the second cassette flanking an internal transposon half side, wherein the internal half side is excisable with a flanking transposon half side.

Additionally, steps of selecting an integration site within the genome of a somatic or germ line cell with first DNA cassette integrated has been added to claims 11 and 35.

Applicants submit that one of ordinary skill in the art would reasonably conclude that Applicants' disclosure adequately described the claimed invention at the time of filing at least inasmuch:

- (1) the structure of the second cassette is depicted in Figure 5 by the present application as it was originally filed,
- (2) the structure of the second cassette is depicted in Figure 7 by the present application as it was originally filed; and
- (3) Applicants describe the donor cassette on paragraph [00067] of the specification. Those of ordinary skill in the art would understand that such a disclosure expressly describes through the figures and description of a donor vector comprising heterospecific site-specific recombinase target sites that are homospecific and in the same orientation with the wild-type/non-mutated or a mutated target site of a site-specific recombinase of the first cassette at one end and a mutated target site of said site-specific recombinase homospecific to said recombinase target site of the first cassette at an other end, with said target sites of the second cassette flanking an internal transposon half side, wherein the internal half side is excisable with a flanking transposon half side. Thus, the present application adequately describes the claimed invention. Applicants thus

respectfully requests favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 112.

In the event that the Office maintains this rejection, Applicants respectfully request, in the interest of its policy of compact prosecution, that the Office explain how the aforementioned portions of the present application fail to communicate to a skilled artisan that Applicants possessed the claimed invention.

**Rejection of Claims 21 and 45 Under 35 U.S.C. §112, second paragraph**

The Examiner rejected claims 21 and 45 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. Those claims have been amended to more clearly define the invention and obviates the §112 rejection.

Specifically claims 21 and 45 have been amended to clarify the operable promoter.

The Applicants respectfully request the rejection under 35 U.S.C. §112, second paragraph be withdrawn.

In view of the foregoing, it is respectfully submitted that pending claims 11-22, 24, 35-46 and 48 define allowable subject matter. Should anything remain in order to place the present application in condition for allowance, the Examiner is kindly invited to contact the undersigned at the telephone number listed below.

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Respectfully submitted,

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